UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, CENTERS FOR MEDICARE AND MEDICAID SERVICES, SEEMA VERMA, in her official capacity as the Administrator of the Centers for Medicare and Medicaid Services, Defendants.	Case No. 7:20-cv-10488-KMK **ECF Case**

REPLY IN SUPPORT OF ORDER TO SHOW CAUSE FOR A PRELIMINARY INJUNCTION, TEMPORARY RESTRAINING ORDER, AND EXPEDITED BRIEFING SCHEDULE

Robert W. Allen, P.C.
Daniel Cellucci
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-4800
Fax: (212) 446-4900
bob.allen@kirkland.com
dan.cellucci@kirkland.com

Paul D. Clement (admitted *pro hac vice*)
George W. Hicks, Jr. (admitted *pro hac vice*)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave. NW
Washington, D.C. 20004
Tel: (202) 389 5000
Fax: (202) 389-5200
paul.clement@kirkland.com
george.hicks@kirkland.com

Counsel for Plaintiff Regeneron Pharmaceuticals, Inc.

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INTRODUCTION

In the government's view, the executive can unilaterally promulgate a "transformative" regulation that will "completely restructure the prescription drug market," affecting millions of Americans and nearly $100 billion in commerce, *without* the congressional authorization it specifically sought and *without* notice and comment on the front end or judicial review on the back end. That is not our system of government, which disclaims executive fiat in favor of separated powers and checks and balances. Perhaps not surprisingly, the government's extraordinary arguments fail at every turn. The government invokes inapposite restrictions on judicial review that apply only to different subchapters and different kinds of challenges. On the merits, it dismisses representations by the Solicitor General and the President, ignores the lengthy delay and felt need for congressional authorization or at least notice and comment that preceded the MFN Rule's promulgation, insists that the Section 1115A mousehole for "testing" "models" authorizes the elephantine MFN Rule, and brushes aside the rule's procedural, substantive, and constitutional flaws. And it contests Regeneron's irreparable harm only by ignoring circuit law and complaining that Regeneron [redacted] The simple reality is that the executive cannot accomplish "transformative" changes that inflict obvious and irreparable harm on the governed without statutory authority, notice and comment, or judicial review. The government's opposition confirms that the MFN Rule is a massive overreach and that Regeneron is entitled to immediate relief.

ARGUMENT

I. REGENERON'S CLAIMS ARE NOT BARRED FROM JUDICIAL REVIEW.

A. The Medicare Statute Does Not Preclude Regeneron's Claims.

The government first contends that 42 U.S.C. §§405, 1395ii preclude this Court's review. That argument fails three times over.

First, those provisions apply to different subchapters and are simply inapplicable here. In relevant part, 42 U.S.C. §405(h) provides that "[n]o action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter," *i.e.*, subchapter II of the Social Security Act. In turn, 42 U.S.C. §1395ii provides that §405(h) "shall also apply *with respect to this subchapter*," with "this subchapter" referring to subchapter XVIII. 42 U.S.C. §1395ii (emphasis added). But Regeneron's claims do not "aris[e] under" subchapter XVIII (or, even more obviously, subchapter II). As the government correctly acknowledges, Regeneron "challenges agency action taken under 42 U.S.C. § 1315a." Opp.7. Section 1315a, however is located *not* in subchapter XVIII but in subchapter XI. The government attempts to elide this problem by asserting that §1315a is "indisputably part of the Medicare statute," *id.*, but that is both wrong and irrelevant. The "Medicare statute" is, in fact, subchapter XVIII, *not* subchapter XI. *See Turecamo v. Comm'r*, 554 F.2d 564, 566 n.1 (2d Cir. 1977) (describing the "Medicare statutory framework" as "Subchapter XVIII of the Social Security Act"). But there is no need to explore the metaphysical depths of what constitutes the "Medicare statute" when the text refers to "this subchapter," *i.e.*, subchapter XVIII, and §1315a lies in a different subchapter. The government's lead jurisdictional argument is thus fatally flawed.[1]

Second, even if the channeling provisions of §§405(h), 1395ii were applicable here, they would not apply to Regeneron's claims, because they channel claims to a reimbursement process that Regeneron cannot access. Section 405 "provides for judicial review of reimbursement decisions" and "requires that claimants first exhaust their administrative remedies." *Council for*

[1] The cases the government invokes, like *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), suffer from the same wrong-subchapter problem. The government briefly cites 42 U.S.C. §1395ff, but that section applies only to appeals from an "initial determination with respect to benefits," which does not remotely describe this case.

Urological Interests v. Sebelius, 668 F.3d 704, 705 (D.C. Cir. 2011). But Regeneron cannot seek reimbursement and has no administrative remedies to exhaust. It is a pharmaceutical manufacturer, and the statute "permit[s] non-providers to seek immediate review in federal court." *Id.* at 711.[2] Indeed, the government's own authority provides that where a party (like Regeneron) cannot avail itself of Medicare's administrative review mechanisms and brings a "challenge[] to agency policy," the claims "fall outside the scope of section 405(h)." *Furlong v. Shalala*, 238 F.3d 227, 230, 234 (2d Cir. 2001); *see also, e.g.*, *Baxter Healthcare Corp. v. Weeks*, 643 F.Supp.2d 111, 115-16 (D.D.C. 2009) (permitting pharmaceutical manufacturer's challenge notwithstanding §405(h), where manufacturer "could not access HHS' administrative review process").[3]

Third, even if Regeneron had administrative remedies to exhaust, the requirement to exhaust them would not be absolute. Exhaustion is excused when the plaintiff can show "(1) that the claim is collateral to a demand for benefits; (2) that exhaustion would be futile; and (3) that plaintiffs would suffer irreparable harm if required to exhaust administrative remedies." *Pavano v. Shalala*, 95 F.3d 147, 150 (2d Cir. 1996). Here, Regeneron's claim is "collateral to a demand for benefits"; indeed, Regeneron does not even *have* a "demand for benefits" but is "challenging the validity of agency regulations." *Id.* Exhaustion would plainly be "futile," as Defendants are not going to invalidate their own rule in an administrative process. And Regeneron faces imminent and irreparable harm, *see* Mem.20-24; pp.14-15, *infra*, so it need not endure the "incontrovertibly grotesque," "ten-year backlog" of the Medicare reimbursement administrative process, *Cumberland Cnty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 49-50 (4th Cir. 2016).

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[2] The government's cases, by contrast, involve a "provider," *Fox Ins. Co. v. Sebelius*, 381 F. App'x 93, 95 (2d Cir. 2010), or "claimant" seeking review of a "Medicare determination," *Pavano v. Shalala*, 95 F.3d 147, 150 (2d Cir. 1996); *see also Ill. Council*, 529 U.S. at 18 ("Medicare patients" and "Medicare providers" must seek agency review).

[3] *National Athletic Trainers' Ass'n v. HHS*, 455 F.3d 500 (5th Cir. 2006), is not to the contrary. That out-of-circuit precedent simply viewed "physicians that employ athletic trainers" as an "adequate proxy" for the trainers "in the administrative review process." *Id.* at 504-05. No comparable relationship exists between physicians and Regeneron.

B. Section 1115A(d)(2) Does Not Strip this Court of Jurisdiction.

As a fallback, the government claims that Section 1115A(d)(2) bars this Court's review. That provision states, in relevant part, that "[t]here shall be no … judicial review" of "the selection of models for testing," "the selection of organizations, sites, or participants to test those models," or "the elements, parameters, scope, and duration of such models." 42 U.S.C. §1315a(d)(2). That limited provision does not begin to insulate the government from a challenge that it has not properly invoked Section 1115A at all and has violated the APA and the Constitution to boot.

1. Regeneron is not quibbling about how the government is testing a model or running the kind of experiment authorized by Section 1115A. Its challenge is far more fundamental—namely, that Section 1115A, and its authorization to test limited models (and its limitations on challenges to the details of those tests), is wholly inapplicable to the kind of "transformative" change envisioned by the MFN Rule. To invoke the judicial review limits of Section 1115A when the principal thrust of the challenge is that Section 1115A is inapplicable is a *non sequitur*. Not surprisingly, courts have consistently permitted challenges like this in the face of judicial review prohibitions, on the basis that "[i]f a no-review provision shields particular types of administrative action, a court … must determine whether the challenged agency action is of the sort shielded from review." *Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004). Put differently, as the D.C. Circuit recently explained, "the jurisdiction-stripping provision does not apply if the agency's action fails to qualify as the kind of action for which review is barred." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020). In such instances, "if the court finds that the agency has acted outside the scope of its statutory mandate," it "ha[s] jurisdiction." *Id.* As "a practical matter," therefore, the merits and the jurisdiction questions "merge[]," and thus "the court can simply skip to the merits question in its analysis." *Id.*; *see also Sw. Airlines Co. v. TSA*, 554 F.3d 1065, 1071 (D.C. Cir. 2009); *COMSAT Corp. v. FCC*, 114 F.3d 223, 226-27 (D.C. Cir. 1997).

The government does not even acknowledge this line of cases, and the government's *lead case* recognizes this caselaw and distinguishes it from the decisions on which the government relies (which involve challenges where the statute and its judicial review restriction concededly apply). *See DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 510 (D.C. Cir. 2019). The more apposite subsequent authority does the same. *See Am. Hosp. Ass'n*, 964 F.3d at 1238-39 (distinguishing cases, including *DCH*, involving "judicial review of agency action for alleged statutory violations even when a statute precludes review"). Accordingly, before the government can invoke Section 1115A(d)(2) here, this Court must first determine whether the MFN Rule is a "test" of a "model" consistent with Congress' intent and principles of constitutional avoidance.[4]

2. Even if Section 1115A limited judicial review, it would not preclude review of Regeneron's constitutional and procedural claims. Foreclosing judicial review of constitutional claims requires "the clearest evocation of congressional intent." *Ralls Corp. v. CFIUS*, 758 F.3d 296, 308 (D.C. Cir. 2014). There is no such "clear and convincing evidence" here, *id.* at 311, and the government does not pretend otherwise. It does not even attempt to grapple with that requirement, instead blithely suggesting that it is somehow "reasonable" to include constitutional claims within the scope of the review bar because Congress "broadly precluded all judicial review related to the selection and scope of models under the statute." Opp.11. Unsurprisingly, that idea is unsupported by any citation, and the idea that the executive could discriminate on the basis of race or religion in its modeling without a judicial reckoning is unfathomable. There is no basis for a different rule when the government engages in retaliation forbidden by the First Amendment or evades the strictures of Art. I §7. Those constitutional challenges must be confronted on the merits.

[4] Even the government's description of its own line of cases is incomplete. The D.C. Circuit has held that "the case law in this circuit is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1173 (D.C. Cir. 2003). Thus, "[w]hen an executive acts *ultra vires*, courts are normally available to reestablish the limits on his authority," even if a "statute[] preclude[s] judicial review." *Id.*

3. The same goes for Regeneron's challenge to forgoing notice-and-comment rulemaking. *See* Opp.12-13. Section 1115A(d)(2) bars review of certain substantive matters, such as "the selection of models," "sites, or participants to test those models," and "the elements, parameters, scope, and duration of such models." 42 U.S.C. §1315a(d)(2). Nothing in that language even purports to bar a claim that CMS violated notice-and-comment requirements or to make CMS' compliance with the APA optional. That silence is compelling given that "statutory limitations on judicial review of agency action should be interpreted narrowly in light of the APA's strong presumption in favor of judicial review." *Sharkey v. Quarantillo*, 541 F.3d 75, 84 (2d Cir. 2008).

Rather than square its argument with the statute's text, the government asserts that in the "Medicare context," any "distinction between procedural and substantive challenges is irrelevant." Opp.12. But there is no "Medicare" exception to the rules of statutory interpretation or judicial review. Indeed, courts considering challenges to Medicare policies have concluded that "review of the *promulgation* of the Secretary's rules and policies [is] separate from the *substance* of any such rules or policies." *Yale New Haven Hosp. v. Azar*, 409 F.Supp.3d 3, 15 (D. Conn. 2019).[5] Congress, moreover, knows how to bar review of procedural claims "but did not include such language in this preclusion statute." *Id.* (citing 42 U.S.C. §1395nn(i)(3)). And Congress routinely carves out procedural claims from preclusion statutes. *See, e.g.*, *Saget v. Trump*, 345 F.Supp.3d 287, 295 (E.D.N.Y. 2018). Try as it might, the government cannot evade confronting the merits.

II. REGENERON IS EXCEEDINGLY LIKELY TO PREVAIL ON THE MERITS.

A. The MFN Rule Was Promulgated Without Notice and Comment.

The government does not dispute that the good-cause exception is "meticulous and

[5] *See also North Oaks Med. Ctr., LLC v. Azar*, 2020 WL 1502185, at *9 (E.D. La. Mar. 25, 2020) ("Contrary to the Secretary's position, it is possible to allege a challenge to notice and comment requirements distinct from a precluded challenge to the Secretary's estimates."); *Fresno Cmty. Hosp. & Med. Ctr. v. Azar*, 370 F.Supp.3d 139, 157-58 (D.D.C. 2019) (review bar does not extend to "alleg[ations] that the Secretary violated the APA").

demanding," "narrowly construed," and "reluctantly countenanced." Mem.8-9. Nor can it deny that a more modest version of the rule was subject to notice and comment years ago or that the rule has a long transition period. It nevertheless insists that it has satisfied the "exacting standards" for good cause. *NRDC v. NHTSA*, 894 F.3d 95, 114 (2d Cir. 2018). But it makes an especially curious argument in support of that claim, affirmatively *disclaiming* any contention that notice and comment would have been "impracticable"—*i.e.*, that an "emergency situation[]" warranted immediate implementation of the MFN Rule, *id.*—and instead resting on the "public interest" exception. Opp.16. The government's choice likely reflects that, in the past several weeks alone, multiple courts have rejected government arguments that COVID-19 makes notice and comment "impracticable." *See, e.g.*, *Purdue Univ. v. Scalia*, 2020 WL 7340156, at *6-10 (D.D.C. Dec. 14, 2020); *Chamber of Commerce v. DHS*, 2020 WL 7043877, at *1-2 (N.D. Cal. Dec. 1, 2020). But the government's Plan B fares no better. The "public interest" condition is met only "in the rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest." *NHTSA*, 894 F.3d at 114 (quoting *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012)). "[F]or the exception to apply, the use of notice and comment must actually harm the public interest." *Id.* The only "recognized permissible use" of the "public interest" prong "is when the notice would enable manipulation," such that "surprise to the parties is necessary." *Id.* at 114 n.13. The idea that a rule contemplated for years and phased in over several more could satisfy that standard is a non-starter.

The government makes no real attempt to satisfy these requirements, and instead invokes a passing statement in *NHTSA*, where the court, when discussing the public-interest prong and finding it inapplicable, noted that "[t]his is not a situation of acute health or safety risk requiring immediate administrative action." *Id.* at 115. That stray reference is not enough to conflate the

"impracticability" and "public-interest" prongs or to transplant "emergency" considerations that *NHTSA* itself recognized are properly understood as part of the "impracticability" prong into the "public-interest" prong. And even if it were, those considerations still would not suffice to turn the pandemic into an excuse for dispensing with orderly and fair administrative proceedings. In fact, neither Defendants nor the President ever invoked COVID-19 (declared a national emergency eight months earlier) as a reason for the rule—including the "new surge" that warranted literally *one sentence* in the MFN Rule (and not a peep during the lengthy remarks accompanying the rule's issuance). *See* 85 Fed. Reg. 76180, 76249 (Nov. 27, 2020).[6] And even that sentence was qualified: CMS stated that the "new surge" in cases "*may* lead to additional hardship." *Id.* (emphasis added). And to put the cherry on the pretextual sundae, the rule actually exempts the one class of treatments actually designed to treat COVID-19. *See id.* at 76191. This is the exact sort of "mismatch" that defeats resort to the good-cause exception. *Chamber of Commerce*, 2020 WL 7043877, at *10.

B. The MFN Rule Lacks Statutory Authorization.

1. The United States just told the Supreme Court that the *entire* Affordable Care Act (ACA) is invalid and of no effect, including Section 1115A. Thus, unless the government wants to disclaim the Solicitor General's argument or concede that it is *un*likely to succeed, it cannot dispute that Regeneron is likely to prevail here. Burying its response in a footnote, *see* Opp.19 n.6, the government never denies that the Solicitor General's success would doom the rule; instead, it observes that "statutes are declared invalid by courts, not positions taken in parties' legal briefs" and that "the Executive Branch continues to operate under the [ACA] while challenges to it are being litigated." *Id.* (citing *United States v. Windsor*, 570 U.S. 744 (2013)). Defendants, however, are not merely enforcing a statute, as in *Windsor*; they are using statutory authority to create a

[6] In fact, the government ignores *all* of the history preceding the MFN Rule's promulgation, effectively asking this Court to "exhibit a naiveté" it need not indulge. *Dep't of Commerce v. New York*, 139 S.Ct. 2551, 2575 (2019).

brand-new "transformative" regime. Moreover, the executive plainly has a duty to "take Care that the Laws be faithfully executed," U.S. Const. art. II, §3, and does not need to wait for a judicial ruling to decline to enforce an unconstitutional or invalid law. At a minimum, given the government's view that the entire ACA, including the authority for the MFN Rule, is invalid, the government cannot dispute that Regeneron has at least raised a "serious question[] going to the merits" of the MFN Rule. *Benihana, Inc. v. Benihana of Tokyo, LLC*, 784 F.3d 887, 895 (2d Cir. 2015).[7] And when it comes time to balance the equities, the government's view, as represented to the Supreme Court, that the statute on which the MFN Rule rests is invalid cannot be ignored.

2. The "transformative" MFN Rule does not set forth a "model" that can be "tested" as contemplated by Section 1115A, and thus it exceeds statutory authority. The government does not deny that the MFN Rule bears no resemblance to the 27 examples listed in Section 1115A. It simply insists that the catchall provision allows it go beyond the 27 examples. But the salient question is, how far beyond? Words in a statute must be "read in their context" so that they fit "into an harmonious whole," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000), and a "catchall" provision only "bring[s] within a statute categories *similar in type* to those specifically enumerated," *Paroline v. United States*, 572 U.S. 434, 447 (2014) (emphasis added). The words "may include" do not convert a statute designed for modest procedural or operational experiments into a blank check authorizing what the HHS Secretary has described as the "most significant single action any administration has ever taken to lower American drug costs."[8]

Even though the ANPRM previously stressed that "the more geographic units available" to serve as control groups, "the better," Mem.4, the government concedes that the nationwide MFN

[7] The government never acknowledges this alternative means of satisfying the first preliminary-injunction factor.
[8] *Trump Administration Announces Prescription Drug Payment Model to Put American Patients First* (Nov. 20, 2020), https://www hhs.gov/about/news/2020/11/20/trump-administration-announces-prescription-drug-payment-model-to-put-american-patients-first html.

Rule has *no* control group. Opp.19. It stresses that the rule "contains a detailed discussion about the method CMS will employ to evaluate the MFN Model," *id.*, but that effort to construct a counterfactual world without the nationwide rule, *see* 85 Fed. Reg. 76232-34, is a far cry from using a control group to test a model. Nor does the MFN Rule, which applies to essentially every Medicare Part B beneficiary in the country, address a "defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. §1315a(b)(2)(A). The government says a "defined population" can include any "beneficiaries who receive an MFN Model drug from an MFN participant where payment for such drug is allowed under the MFN Model." Opp.17. But under that view, "everyone on the planet" is a "defined population." A statute addressed to testing models on defined, underserved subgroups clearly requires a limited population, not everyone with Medicare eligibility.

Indeed, even if millions of people with nothing in common could count as a "defined population," the government admits that not everyone in that massive group suffers from "deficits in care." Instead, it argues that a "defined population" with "potentially avoidable expenditures" for that "defined population" by itself is enough. Opp.18 n.5. But that is not what the statute says. "[P]otentially avoidable expenditures" is plainly one of two things that can result from "deficits in care." CMS' interpretation requires separating "deficits in care" from "potentially avoidable expenditures," contrary to "basic rules of English grammar." *Jordan v. U.S. Dep't of Justice*, 591 F.2d 753, 764 (D.C. Cir. 1978) (en banc). That view not only is grammatically wrong, but would dramatically expand CMS' authority to pursue anything it claimed reduced expenditures.

3. Finally, the government's argument suffers from an even more basic flaw: Congress did not authorize "transformative" and elephantine changes in drug prices via the mousehole of Section 1115A. Yet "enormous and transformative" rules require "clear congressional

authorization." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014). The government insists (at Opp.20), as it must, that Congress "explicit[ly]" authorized what the President has called "the most far-reaching prescription drug reforms ever issued." Mem.5. Nothing in the text, structure, or purpose of Section 1115A supports that claim. To the contrary, if Section 1115A already authorized the MFN Rule, the President's prior efforts to obtain actual statutory authority for such a massive change, in his State of the Union address no less, would have been unnecessary.

C. The MFN Rule is Arbitrary and Capricious.

The MFN Rule is arbitrary and capricious for three independent reasons. First, Defendants failed to consider the specific factors that Congress directed them to consider. *See* Mem.15-16. The government has no response, apparently conceding the point. *See Palmieri v. Lynch*, 392 F.3d 73, 86-87 (2d Cir. 2004). Second, Defendants failed to consider several of the most significant problems when promulgating the MFN Rule. The government states that agencies are not required to address "every possible counterargument," Opp.21, but it does not (and cannot) dispute that agencies *are* required to consider all "important aspect[s] of the problem" before them, *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Nor does it dispute that the aspects that Regeneron identified—adverse effects on innovation, drug companies' longstanding reliance on statutory law, and some manufacturers' (like Regeneron's) lack of control over foreign drug prices—are critically important. The agency thus had to explain why it promulgated the rule despite those substantial drawbacks, but failed to do so. Indeed, while the government notes that the rule "spans more than 80 pages" and "addressed important issues," Opp.20-21, it never actually claims that the rule addressed any of the specific issues Regeneron identified. And *post hoc* rationales of counsel cannot fill that gap. *State Farm*, 463 U.S. at 50.

Third, Defendants promulgated the rule as retaliation for the industry's failure to support the President's reelection. Other than claiming to "debunk" the existence of a retaliatory motive,

but see infra, the government merely notes that *Department of Commerce v. New York*, 139 S.Ct. 2551 (2019), did not contain a factual finding of animus. What is relevant about *Department of Commerce*, however, is not its specific facts but its legal conclusion that agency action is arbitrary and capricious if its true motivation differs from the justifications formally cited by the agency. *Id.* at 2575. As the President's own statements make clear, that is precisely the case here.

D. The MFN Rule Is Unconstitutional.

1. The MFN Rule violates bicameralism and presentment. The government argues that the multiple provisions that the rule waives still have "legal force and effect" because MFN pricing will not apply to every single drug. Opp.22. But *Clinton v. City of New York*, 524 U.S. 417 (1998), did not hold that the Executive is free to cancel statutory provisions as long as they retain some modicum of vestigial force. Indeed, the provisions the President canceled still had "some continuing financial effect on the Government," and yet the Court still found a constitutional violation. *Id.* at 441. Wherever the line between a permissible waiver and an impermissible exercise of legislative power may fall, Defendants' attempt here to not just *waive* statutory provisions (as in *Clinton*) but broadly *implement* a system that Congress has repeatedly *rejected* falls on the wrong side of that line.[9] The government also argues that the waived provisions retain meaningful force because payments for covered drugs "in 2021" will be based on a blend of the ASP and MFN prices. Opp.23. While true for 2021, the MFN price alone will control by 2024, *see* 85 Fed. Reg. 76254, and a phased-in line-item veto is no more constitutional. Finally, the government argues that the Secretary "*executed* rather than rejected" Congress' will, Opp.23, but Congress' will about drug prices is reflected elsewhere, *see* 42 U.S.C. §1395w-3a, and Congress

[9] The cases the government cites are not remotely comparable; they address narrow waivers in the foreign affairs realm. *See Republic of Iraq v. Beaty*, 556 U.S. 848 (2009) (waiving one provision for one country); *Defs. of Wildlife v. Chertoff*, 527 F.Supp.2d 119 (D.D.C. 2007) (waiving environmental laws for one immigration-related project).

also provided authority for the line-item veto deemed unconstitutional in *Clinton*.

2. The MFN Rule violates the First Amendment. The government's response is astonishingly weak. It does not dispute that issuing a rule as retaliation for protected speech would violate the First Amendment, and it does not defend the President's remarks as non-retaliatory. Instead, the government improbably denies a "nexus" between the President's statements and the Secretary's promulgation of the rule. Opp.24. That assertion blinks both theory and reality. As a matter of theory, one this Administration routinely embraces: "The entire 'executive Power' belongs to the President alone," *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2197 (2020) (accepting government's argument), and the unelected agency head draws his authority from the President, not vice-versa. As a matter of fact, the nexus between the President's remarks and the Secretary's promulgation of the rule is glaringly obvious. The rule follows from an Executive Order directing the Secretary to "immediately" implement most-favored-nation pricing. 85 Fed. Reg. 59649 (Sept. 13, 2020). The President explained that he "ha[d] to" follow through on the order with the rule because "[b]ig pharma ran millions of dollars of negative advertisements against me during the campaign." And the effort to distance the Secretary from the President is mystifying given that Secretary Azar, upon the rule's issuance, emphasized the President's involvement and criticized drug companies for "run[ning] millions of dollars in ads against the President's drug pricing initiatives."[10] Once again, this Court should reject the government's invitation to "exhibit … naiveté." *Dep't of Commerce*, 139 S.Ct. at 2575.

3. At a minimum, the MFN Rule raises "serious constitutional doubts," requiring this Court to construe Section 1115A narrowly. Mem.19-20. The government disputes neither this principle

[10] Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans (Nov. 20, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans.

of law nor its application to this case, confirming the lack of statutory authorization for the rule.

III. REGENERON WILL SUFFER IRREPARABLE HARM, AND THE BALANCE OF EQUITIES FAVORS RELIEF.

The government concedes that, in the Second Circuit, the inability to recover monetary loss due to sovereign immunity constitutes irreparable harm. *See* Opp.24-25; Mem.22-23. Because Regeneron will incur massive monetary losses from the MFN Rule that are unrecoverable due to Defendants' sovereign immunity, it satisfies this prong of the preliminary-injunction test.

The government's half-hearted response does not alter this outcome. First, the government contends that the injury must be "actual and imminent," not "remote" or "speculative." Opp.25. But the declaration submitted by Regeneron's Vice President of Market Access, Richard O'Neal, extensively describes the "actual and imminent" monetary injury to Regeneron. Far from making "conclusory assertion[s]," *id.*, the declaration painstakingly walks through *how* and *why* the rule will cause imminent and irreparable harm. *See* O'Neal Dec. ¶¶6-33. The government quibbles that the declaration does not explain "how it calculated its anticipated losses," Opp.25, but Mr. O'Neal explains that he used the MFN Rule's own methodology. The government complains that Regeneron provided losses only for "the entirety of 2021," giving "little insight into the magnitude of its loss during the pendency of this case." *Id.* But if harm must be imminent to count, starting with 2021 seems eminently reasonable, [redacted] Only the federal government could doubt that is "considerable." Opp.25.

The government likewise does not contest Regeneron's authority holding that injuries to "reputation, good will, and business opportunities" constitute additional irreparable harm. Mem.23-24 (citing cases). And it does not (and could not) dispute that providers faced with reimbursement rates below their acquisition costs will switch from EYLEA to competitor products not subject to the MFN Rule. Instead, the government doubts Mr. O'Neal's unrebutted statement

that at least some patients switched from EYLEA will not return. Opp.26. But that proposition is both self-evident and well within Mr. O'Neal's expertise. And new patients never prescribed EYLEA present an even more obvious lost opportunity. The government quibbles with Mr. O'Neal's statements regarding how reduced prices and revenues will translate to reduced R&D budgets. Opp.26. If the government needs basic principles of supply and demand explained, that may explain the MFN Rule, but it does not detract from Regeneron's showing of irreparable injury.

Regeneron's constitutional and notice injuries are irreparable as well. The government's cases claiming a distinction between "personal" and "structural" rights all predate *Bond v. United States*, 564 U.S. 211 (2011), which held that "[t]he structural principles secured by the separation of powers protect the individual as well," *id.* at 222, and they ignore the First Amendment claim. As for notice, courts have held that a violation of an affected party's notice-and-comment rights is irreparable where, as here, the party has some "immediate" interest "at stake." *California v. HHS*, 281 F.Supp.3d 806, 830 (N.D. Cal. 2017).

Finally, Regeneron's explanation of how the balance of the equities and public interest favor immediately enjoining the MFN Rule, *see* Mem.24-25, stands unrebutted. The harms to Regeneron and third parties are massive, and the government's interest in maintaining a rule that it previously recognized needed at least notice and comment—and, before that, statutory authorization—is close to nil, especially where the government has told the Supreme Court that its statutory authority no longer exists. The need for preliminary relief is clear.[11]

CONCLUSION

The Court should grant a preliminary injunction enjoining the MFN Rule, including a temporary restraining order preventing Defendants from implementing or enforcing the rule.

[11] The government suggests that Regeneron "appears to seek nationwide relief." Opp.28. But Regeneron has never sought nationwide relief for others; it seeks only to enjoin the MFN Rule as applied to Regeneron.

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Respectfully submitted,

/s/ *Robert W. Allen, P.C.*

Robert W. Allen, P.C.
Daniel Cellucci
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-4800
Fax: (212) 446-4900
bob.allen@kirkland.com
dan.cellucci@kirkland.com

Paul D. Clement (admitted *pro hac vice*)
George W. Hicks, Jr. (admitted *pro hac vice*)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave. NW
Washington, D.C. 20004
Tel: (202) 389 5000
Fax: (202) 389-5200
paul.clement@kirkland.com
george.hicks@kirkland.com

Counsel for Plaintiff Regeneron Pharmaceuticals, Inc.